

PATENT COOPERATION TREATY

PCT

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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 10589-007-228	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/US02/11757	International filing date (day/month/year) 11 April 2002 (11.04.2002)	Priority date (day/month/year) 11 April 2001 (11.04.2001)
International Patent Classification (IPC) or national classification and IPC IPC(7): C12Q 1/68; C07H 12/02; G01N 27/26 and US CL.: 435/6; 536/23.1; 204/451		
Applicant PTC THERAPEUTICS, INC		
<p>1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>3</u> sheets, including this cover sheet.</p> <p><input type="checkbox"/> This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of <u> </u> sheets.</p> <p>3. This report contains indications relating to the following items:</p> <p>I <input checked="" type="checkbox"/> Basis of the report</p> <p>II <input type="checkbox"/> Priority</p> <p>III <input type="checkbox"/> Non-establishment of report with regard to novelty, inventive step and industrial applicability</p> <p>IV <input type="checkbox"/> Lack of unity of invention</p> <p>V <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p>VI <input type="checkbox"/> Certain documents cited</p> <p>VII <input type="checkbox"/> Certain defects in the international application</p> <p>VIII <input type="checkbox"/> Certain observations on the international application</p>		
Date of submission of the demand 07 NOVEMBER 2002	Date of completion of this report 01 May 2003 (01.05.2003)	
Name and mailing address of the IPEA/US Mail Stop PCT, Attn: IPEA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703)305-3230	Authorized officer Jon D Epperson Telephone No. (703) 308-2423	

Form PCT/IPEA/409 (cover sheet)(July 1998)

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US02/11757

I. Basis of the report

1. With regard to the **elements** of the international application:*

- ☒ the international application as originally filed.
- ☒ the description:
pages 1-96 as originally filed
pages NONE, filed with the demand
pages NONE, filed with the letter of _____.
- ☒ the claims:
pages 97 as originally filed
pages NONE, as amended (together with any statement) under Article 19
pages NONE, filed with the demand
pages NONE, filed with the letter of _____.
- ☒ the drawings:
pages 1-5 as originally filed
pages NONE, filed with the demand
pages NONE, filed with the letter of _____.
- ☒ the sequence listing part of the description:
pages 1-45 as originally filed
pages NONE, filed with the demand
pages NONE, filed with the letter of _____.

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language _____ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☒ contained in the international application in printed form.
- ☒ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages NONE
- ☐ the claims, Nos. NONE
- ☐ the drawings, sheets/fig NONE

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/US02/11757**V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement****1. STATEMENT**

Novelty (N)	Claims <u>1</u>	YES
	Claims <u>NONE</u>	NO
Inventive Step (IS)	Claims <u>NONE</u>	YES
	Claims <u>1</u>	NO
Industrial Applicability (IA)	Claims <u>1</u>	YES
	Claims <u>NONE</u>	NO

2. CITATIONS AND EXPLANATIONS

Claim 1 lacks an inventive step under PCT Article 33(3) as being obvious over Crooke et al in view of Cook et al.

Crooke et al discloses a method for screening RNA target molecules against a combinatorial library of ligands wherein mass spectroscopy is used to identify the ligands (see Crooke et al, column 40, example 11). Furthermore, the RNA and ligand molecules have an "intrinsic mass label" (see column 41, first paragraph). Crooke et al also teaches the use of "hyphenated" technology where a separation step including CE is used before analysis by the mass spectrometer (see Crooke et al, column 12, last paragraph).

Although Crooke et al states that any separation method may be used along with mass spectrometry including capillary electrophoresis, it does not explicitly mention the use of CGE i.e., capillary "gel" electrophoresis in these types of "hyphenated" systems.

However, Cook et al discloses the use of CGE for the analysis of RNA (see Cook et al, column 11, lines 14-22). It would have been obvious to use CGE as taught by Cook et al in a "hyphenated" system for the screening of RNA against a library of ligands us mass spectroscopy to analyze said ligands as taught by Crooke et al because Crooke et al explicitly states that any separation technique can be used, which would encompass CGE and specifically points to a related separation technique i.e., CE. Furthermore, one of skill in the art would have been motivated to use the CGE technique in conjunction with the mass spectrometer to increase the sensitivity and accuracy of the measurement by removing potential contaminants.

Claim 1 has industrial applicability because the method can be used in the pharmaceutical industry.

----- NEW CITATIONS -----